REMARKS

This response is filed together with a Request for Continued Examination under 37 CFR 1.114. This response is accompanied by new evidence in the form of a declaration of Dr. Armitage under 37 CFR 1.132.

Claims 1-7, 9-17, and 19 are pending in the application. No amendments are presented with this response. In view of the remarks below, favorable reconsideration of the application is respectfully requested.

Given the posture of the present prosecution, Applicants respectfully request that, should the Examiner determine that the application is still not in condition for allowance after reviewing this response, she contact the undersigned to discuss a future course of action before issuing another written action.

I. REJECTIONS OF CLAIMS 1-7 AND 9-18 UNDER 35 U.S.C. § 102(b)

Claims 1-7 and 9-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,725,586 to Lindstrom et al. ("Lindstrom"). Applicants respectfully traverse.

The claims as presented pertain to compositions that do not include material amounts of chondroitin sulfate or 2-mercaptoethanol. However, these components are essential to the functioning of Lindstrom's composition. Further, their presence, in functionally active amounts, would materially alter the basic and novel characteristics of the solutions recited in the pending claims. Applicants' position on this was clearly articulated in their previous response filed November 15, 2004.

In the Final Office Action mailed February 7, 2005, the Examiner addressed Applicants' position as follows:

> Applicant in his remarks argues that the presented claimed compositions do not include chondroitin sulfate or 2-mercaptoethanol. However, applicant has failed to demonstrate that the addition of such agents to the claimed composition would materially alter the effectiveness of the claimed composition. There is no evidence of record to show that the claimed composition would function differently if 2-mercaptoethanol or chondroitin sulfate was added to such composition. Thus, for the above reasons and the reasons discussed previously the prior rejection stands.

Upon receiving the Final Action, Applicants undersigned attorney immediately called the Examiner to further discuss the rejection. The Examiner explained that in her opinion the Applicants have not demonstrated that the presence of chondroitin sulfate or 2-mercaptoethanol would "materially alter the effectiveness of the claimed composition." During the interview the Examiner explained that she might be persuaded by experimental evidence in the form of a declaration showing that these additives (chondroitin sulfate or 2-mercaptoethanol) materially change the desired properties of the irrigating solution. Such properties might include stability, etc. Applicants appreciate the courtesy of this telephonic interview extended by the Examiner on February 28, 2004.

With this response, Applicants submit a declaration of Dr. Armitage presenting experimental evidence, as requested by the Examiner, showing that the presence of chondroitin sulfate and 2-mercaptoethanol materially alter the claimed ocular irrigating solution and method of irrigating the eye.

In his declaration, Dr. Armitage describes experiments in which an irrigating solution of the claims was prepared both with and without chondroitin sulfate or 2-mercaptoethanol. The solutions were then tested for stability during autoclaving. As explained earlier in prosecution, autoclaving is a step frequently performed to sterilize irrigating solutions prior to use in commercial settings.

The carefully conducted experiments of Dr. Armitage demonstrate that chondroitin sulfate or 2-mercaptoethanol or both compounds is heat-labile and unable to survive sterilization by autoclaving. Hence the addition of such agents to the claimed composition has been shown to materially alter the effectiveness of the claimed composition. The experimental results clearly demonstrate that the claimed composition would function differently if 2-mercaptoethanol or chondroitin sulfate were added to such composition.

A person skilled in the art would be highly unlikely to consider using the Lindstrom composition after autoclaving (with the decomposition products in it) as an eye irrigation solution.

As explained before, advantages of the invention include the absence of various components considered essential in prior art ocular irrigation solutions. Thus, a basic feature of the claimed invention is use of a simple solution free of unnecessary extra components that add expense, will not withstand sterilization by autoclaving, may even degrade over time. This feature is explicitly claimed by use of the "consisting essentially of" transitional language when characterizing the solution. See MPEP 2111.03. The working examples in the present invention further support this feature.

As explained earlier in Applicants' earlier responses, the surgical solution of Lindstrom requires at least a source of electrolytes in the form of a balanced salt solution, chondroitin

sulfate, HEPES buffer, and 2-mercaptoethanol. This is the most basic composition described in the Lindstrom et al. patent.

It is also worth noting that Lindstrom does not itself mention autoclaving. While the broadest pending claims of the present invention do not require autoclaving, the ability to autoclave a solution is an important advantage of the invention. It is surprising that Lindstrom does not mention autoclaving since one might expect that if Lindstrom's solution were autoclavable, this would have been mentioned, especially given that Lindstrom et al. characterize their composition as an improvement over the BSS Plus solution which is sterilized by autoclaving.

In summary, 2-mercaptoethanol and chondroitin sulfate are essential Lindstrom. They are not part of the presently claimed invention. As explained and demonstrated, they would materially change claimed invention, both in terms of added expense and instability during autoclaving. It is well known that claims employing the "consisting essentially of" transitional language are interpreted to cover compositions that include only the recited compounds as active components. In present case, chondroitin sulfate and 2-mercaptoethanol can only be viewed as active components based on their roles in the Lindstrom patent.

Withdrawal of the rejections is respectfully requested.

II. REJECTION OF CLAIM 19 UNDER 35 U.S.C. § 103

Claim 19 stands rejected under 35 U.S.C. § 103 as being obvious over Lindstrom in view of U.S. Patent No. 5,403,841 to Lang et al. ("Lang"). Lang discloses no composition meeting the requirements of the pending claims. Lang does not, therefore, overcome the deficiencies of Lindstrom and does not preclude patentability of claim 19 or any other pending claim.

III. CONCLUSION

Applicants believe that all pending claims are in condition for allowance, and respectfully request a Notice of Allowance at an early date. The Examiner is encouraged to contact the undersigned at the telephone number below if any issues remain.

Respectfully submitted,
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